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10/583,062	01/31/2007	Andreas Calatzis	1406/354	5988

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EXAMINER	
WALLENHORST, MAUREEN	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,062	CALATZIS ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8,11-20,22-26 and 28-30* is/are pending in the application.

4a) Of the above claim(s) *25,26 and 28-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,11-20 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/17/06, 8/31/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election of Group I, claims 1-6, 8, 11-20 and 22-24 in the reply filed on April 23, 2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprising" and "said". Correction is required. See MPEP § 608.01(b).

4. Claims 1-6, 8, 11-20 and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Part a) of claim 1 is indefinite and incomplete since it is not clear how the receiving portion of the cell and the plug or jack portion are structurally related to one another. It is not clear how the receiving portion of the cell is physically situated in relation to the plug or jack portion. Part c) of claim 1 is indefinite since it is not clear whether the one end of the two electrodes that form a sensor unit are physically located in the blood sample that is located in the receiving portion of the cell. Part c) of claim 1 is also indefinite since it is not clear how the opposite end of the at least one electrode pair forms a plug or jack portion when part a) of claim

1 recites that a portion of the structure of the cell forms a plug or jack portion. Is the opposite end of the at least one electrode pair located within the plug or jack portion of the cell recited in part a) of claim 1?

Regarding claim 2, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). See this same problem in claims 8 and 19.

On line 2 of claim 4, the phrase "the open face side" lacks antecedent basis since claim 4 depends from claim 1, not claim 3.

On lines 3-4 of claim 14, the phrase "the platelet aggregation" lacks antecedent basis.

In claim 19, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See this same problem in claims 20, 22 and 23. Claim 19 is also indefinite since it is not clear whether the recited amounts of the silver are percentages by weight or percentages by volume. Also, the phrases "0,2 to 2% silver" and "0,9% silver" should be changed to --0.2 to 2% silver-- and --0.9% silver--.

Regarding claim 20, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). See this same problem with the phrase "such like" on line 3 of claim 20. On line 3 of claim 20, the phrase "0,5 to 20 g/kg" should be changed to --0.5 to 20 g/kg--.

In claim 22, the phrase "the electrode wires" lacks antecedent basis. On line 2 of claim 22, the phrase "about 0,1 to 0,5 mm, preferably 0,3 mm" should be changed to --about 0.1 to 0.5 mm, preferably 0.3 mm--.

On lines 1-2 of claim 23, the phrase "the means" should be changed to --the means for circulating-- so as to use the same terminology as used in claim 1.

Claim 23 is indefinite since it recites the trademark "TEFLON", and trademarks are not permitted to be recited in patent claims since they are subject to change over time. Regarding claim 23, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-3, 8, 12-17 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoner et al (US 3,840,806, submitted in the IDS filed on July 17, 2006) in view of Cardinal et al (US 4,319,194, submitted in the IDS filed on August 31, 2009).

Stoner et al teach of a device for analyzing the coagulation of blood. In the embodiment depicted in Figure 7 of Stoner et al, the device comprises a cell having a receiving portion 60 for receiving a blood sample to be analyzed, and a plug or jack portion 74. The receiving portion 60

is made out of a conventional plastic material such as polyethylene (claim 2), and is of a cylindrical shape with an open face side (claim 3). A pair of electrodes 68 is positioned within the receiving portion 60 for contacting the sample of blood within the portion 60. The electrodes are preferably constructed of gold and are located about 2.0 mm from one another. The electrodes 68 are mounted in an electrode holder 72 that is either adhered to a lower surface of the receiving portion 60 or formed integral therewith. Thus, when the electrode holder is formed integrally with the receiving portion 60, it is also formed of a conventional plastic material such as polyethylene (claim 8) similar to the receiving portion 60. The plug portion 74 is rigidly mounted in the lower outwardly facing surface of the electrode holder 72. The plug portion 74 serves to couple the electrodes 68 to a power source and sensor unit of an analyzer 76. The analyzer 76 is depicted in Figure 8 of Stoner et al, and includes a plug 78 mounted on its upper surface for physically receiving the receiving portion 60 and for providing electrical connection with the plug portion 74 coupled to the electrodes 68. Thus, the device taught by Stoner et al comprises a cell having a receiving portion (60) for receiving a blood sample, a plug portion (74), and an electrode holder 72 having at least one incorporated electrode pair 68 (claim 1). The electrodes of the pair are positioned parallel to each other and spaced apart from each other (claim 16). See Figures 7-8, lines 47-67 in column 7 and lines 1-18 in column 8 of Stoner et al. Stoner et al fail to teach that the device for analyzing blood comprises a means for circulating the blood sample within the receiving portion 60, fail to teach that more than one electrode pair may be included in the apparatus and attached to the electrode holder 72, and fail to teach that the diameter of the electrodes is between about 0.1-0.5 mm.

Cardinal et al teach of a device for monitoring blood coagulation and platelet aggregation in a blood sample. The device comprises a cuvette 1 in which a blood sample is located, and two electrodes 4A and 4B inserted into the cuvette from a lid 5 located over the opening to the cuvette 1. The electrodes have a diameter of about 0.25 mm. During monitoring of the platelet aggregation in the blood sample located within the cuvette 1, the blood is stirred by means of a stirring element or rod 3 driven in a conventional manner by a magnetic coupling with a rotating drive member located outside the cuvette 1. The stirring means or rod 3 is preferably made of Teflon or coated with Teflon. See Figure 3, lines 9-40 in column 4 and lines 50-59 in column 5 of Cardinal et al.

Based upon the combination of Stoner et al and Cardinal et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to include a means for circulating the blood sample within the receiving portion 60 of the device taught by Stoner et al, such as the stir bar taught by Cardinal et al, since Cardinal et al teach that it is advantageous to stir a blood sample in a container being analyzed for blood coagulation or platelet aggregation in order to increase the contact between the platelets in the blood sample and the electrodes within the container. With regards to claims 12-15 and 17, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide more than one electrode pair in the electrode holder 72 taught by Stoner et al, wherein the electrodes of each pair are positioned parallel to one another, so as to provide for more than one measurement result and to obtain measurement results at different locations within the blood sample. In addition, the mere duplication of parts without any new or unexpected results is within the skill of the routineer in the art. See In re Harza, 124 USPQ 378 (CCPA 1960). With regards to claim 22, it would have

been obvious to one of ordinary skill in the art to use electrodes having a diameter of between 0.1-0.5 mm as the electrodes 68 in the device taught by Stoner et al since Cardinal et al teach that electrodes in a similar type of device for analyzing blood coagulation conventionally have a diameter of about 0.25 mm, which size serves to obtain accurate measurement results.

8. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoner et al in view of Cardinal et al as applied to claims 1-3, 8, 12-17 and 22-23 above, and further in view of Sage Jr et al (US 6,584,349). For a teaching of Stoner et al and Cardinal et al, see previous paragraphs in this Office action. Stoner et al fail to teach that the electrodes 68 in the device can be made of a first material such as copper that is coated with a second material such as a precious metal like silver or gold.

Sage Jr et al teach of an apparatus having an electrode therein that is formed from a low-cost bulk base metal which includes a coating of a precious metal thereon. The apparatus includes an anode 14 therein that is formed of a bulk base metal such as copper or a copper alloy. The bulk base metal is coated with a precious metal 144 such as silver. The use of copper as the bulk base metal provides an effective, low cost anode. The silver coating protects against the copper reacting with a chemical prior to use and provides stability to the anode to promote a longer shelf life. Sage Jr et a teach that such an electrode has been found to exhibit good shelf-life stability as well as good voltage characteristics and stability over a prolonged period of use. In addition, by using copper as the bulk base metal of the electrode, significant cost savings are achieved. See lines 54-67 in column 2, lines 1-12 in column 3 and lines 28-59 in Column 6 of Sage Jr et al.

Based upon the combination of Stoner et al, Cardinal et al and Sage Jr et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use as the electrodes 68 in the device taught by Stoner et al electrodes that are formed of a first material such as copper that is coated with a second material such as a precious metal like silver or gold, similar to the electrodes taught by Sage Jr et al, since Sage Jr et al teach that such electrodes provide significant savings in terms of cost over other electrodes such as the gold electrodes used in the device of Stoner et al, and also teach that such electrodes exhibit good shelf-life stability as well as good voltage characteristics and stability over a prolonged period of use.

9. Claims 4-6, 11 and 24 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims since none of the prior art of record teaches or fairly suggests a cartridge device for analyzing blood having the features recited in independent claim 1 in combination with a funnel portion connected to the open face side of the receiving portion of the device, guide rails on the funnel portion and a stopping wall between the funnel portion and the plug portion of the device, an electrode holder in the device that is L-shaped, and wherein the device is plugged into a standard RJ12 plug be means of the plug or jack portion.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Rosenthal et al who teach of an apparatus for measuring resistance of blood during clotting; Martin et al who teach of a device for determining the clotting time of blood; Josefsen et al who teach of a device containing electrodes for measuring characteristics of

blood samples; and Roussean who teaches of a device for detecting a change in the viscosity of a liquid.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim, can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1797

mmw

May 6, 2010

/Maureen M. Wallenhorst/

Primary Examiner, Art Unit 1797